PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 :
G01N 33/487, 33/49, 33/52, 33/53

A1

(11) International Publication Number: **WO 95/15493**

(43) International Publication Date: 8 June 1995 (08.06.95)

(21) International Application Number: PCT/US94/12623

(22) International Filing Date: 2 November 1994 (02.11.94)

(30) Priority Data:
08/146,307 2 November 1993 (02.11.93) US

(71) Applicant: ANONYMOUS TEST SERVICES, INC. [US/US]; 2550 West Golf Road, Rolling Meadows, IL 60008-4051 (US).

(72) Inventor: QUATTROCCHI, Richard, A.; 115 Redwood Lane, Barrington, IL 60010 (US).

(74) Agent: HARBST, John, W.; Rudnick & Wolfe, Suite 1800, 203 North LaSalle Street, Chicago, IL 60601-1293 (US).

(81) Designated States: AU, BR, CA, JP, KP, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published
With international search report.

(54) Title: METHOD AND SYSTEM FOR ANONYMOUSLY TESTING FOR A HUMAN MALADY

(57) Abstract

An anonymous testing system for taking a sample of body fluid to be tested, the sample is acquired in private and sent for analyzation to obtain results. The system comprises a test kit for creating a sample of body fluid, a personal code for anonymously identifying the sample and the person, and an electronic file telephonically created and accessed by the person taking the test and identified by the personal code. The electronic file contains the test results determined by analyzation. There is also a method of anonymously testing of a person's body fluid in private and the results to be anonymously received by the person without having to reveal his or her identification. The method comprises the steps of procuring a test kit for taking a sample of the body fluid. The test kit has a personal code associated therewith and equipment to take the sample. The person uses the equipment to obtain the sample and sends the sample with the personal code to a testing site. The person also creates a personal electronic file telephonically; the file is identified by the personal code. The sample is identified by the personal code. At the testing site, the sample is tested, and the results are updated into the electronic file with a corresponding personal code. The person later accesses the electronic file telephonically to obtain his or her results.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	GB	United Kingdom	MR	Mauritania
AU	Australia	GE	Georgia	MW	Malawi
BB	Barbados	GN	Guinea	NE	Niger
BE	Belgium	GR	Greece	NL	Netherlands
BF	Burkina Faso	HU	Hungary	NO	Norway
BG	Bulgaria	IE	Ireland	NZ	New Zealand
BJ	Benin	IT	Italy	PL	Poland
BR	Brazil	JP	Japan	PT	Portugal
BY	Belarus	KE	Kenya	RO	Romania
CA	Canada	KG	Kyrgystan	RU	Russian Federation
CF	Central African Republic	KP	Democratic People's Republic of Korea	SD	Sudan
CG	Congo			SE	Sweden
CH	Switzerland	KR	Republic of Korea	SI	Slovenia
CI	Côte d'Ivoire	KZ	Kazakhstan	SK	Slovakia
CM	Cameroon	LI	Liechtenstein	SN	Senegal
CN	China	LK	Sri Lanka	TD	Chad
CS	Czechoslovakia	LU	Luxembourg	TG	Togo
CZ	Czech Republic	LV	Latvia	TJ	Tajikistan
DE	Germany	MC	Monaco	TT	Trinidad and Tobago
DK	Denmark	MD	Republic of Moldova	UA	Ukraine
ES	Spain	MG	Madagascar	US	United States of America
FI	Finland	ML	Mali	UZ	Uzbekistan
FR	France	MN	Mongolia	VN	Viet Nam
GA	Gabon				

METHOD AND SYSTEM FOR ANONYMOUSLY TESTING FOR A HUMAN MALADY

FIELD OF THE INVENTION

The present invention relates to a method and system for testing for human malady and, more particularly, to a method and system for testing for the Human Immunodeficiency Virus (HIV) which is responsible for Acquired Immune Deficiency Syndrome (AIDS).

BACKGROUND OF THE INVENTION

Many of today's human maladies are highly contagious, readily transmissible, and, in some cases, medical cures have not yet been discovered. For example, AIDS has become a serious health threat and has reached epidemic proportions around the world. Presently, there is no cure for AIDS or for the HIV virus that causes AIDS. While having the HIV virus does not necessarily mean that a person will contract AIDS, because of its contagiousness and transmissibility, it is important to know whether a person is infected with the HIV virus.

Both HIV and AIDS are not inherited but are acquired. HIV is passed from one person to another as through the transference body fluid such as infected blood, semen or vaginal fluids. Accordingly, HIV is often transmitted by unprotected vaginal, anal, or oral sexual intercourse, or through the sharing of hypodermic needles by intravenous drug users. Infants can also acquire HIV from their mothers during pregnancy or delivery.

A fundamental step in preventing the spread of HIV and AIDS is to inform those people who are infected about their condition. Hopefully, once someone knows they are

infected they will take extra precaution in their activities thereby containing the spread of the disease. While a cure for the HIV and AIDS has not yet been found, the medical community has developed accurate tests to detect the presence of HIV antibodies in the blood stream. The most recognized tests are known as the Enzyme Linked Immunosorbent Assay (ELISA) and the Western Blot tests. By combining these highly effective tests, test results can be approximately 99.7 percent accurate.

HIV antibodies develop in the blood stream after someone is infected with HIV. These antibodies can take up to six (6) months to develop before being detected by the ELISA and Western Blot tests. Accordingly, immediate infection with HIV virus is not necessarily detectable.

Even though the tests for HIV are highly accurate, many people are reluctant to have themselves tested. A fundamental reason for this reluctance is fear: The fear of death and the stigma of having AIDS. Not only do people with AIDS have to deal with this devastating and terminal disease, but they also have to combat other people's prejudices and fear.

The general populace's prejudice and fear stem from many different things. One reason is general discrimination towards homosexual men. The homosexual male population was one of the first communities heavily affected by AIDS. Accordingly, AIDS became known as a gay disease and people with AIDS are assumed to be gay.

A deeper element to the problem is based in the public's general lack of understanding about how one can contract the HIV virus. Casual contact does not promote the spread of the disease. However, until the public understands this, people with AIDS tend to be ostracized from their community at a time when they need the most

support. Adults have been fired from their jobs, and children have been locked out of their schools.

Problems for people with HIV and AIDS has also presented itself in the medical community. People with HIV and AIDS can find it hard to find a doctor that will treat them, and quite often insurance companies are unwilling to pay for the necessary and expensive treatments that AIDS patients often require.

Taking into account these factors, the decision to take an HIV antibody test is a difficult choice to make. However, there are many good reasons to do so, such as: A need to know; anxiety relief; protecting oneself; protecting one's sexual partners; protecting one's children; and obtaining early medical intervention.

However, people are still afraid to take a test for the fear that others will find out if the test is positive. There are procedures to ensure that one's HIV status is protected from others. There is no system or method, however, that completely protects the identity of the person who has submitted a blood sample to be tested.

In the past, systems have been developed that attempt to protect individuals from the general dissemination of test results. Medical practices and policies, like the doctor-patient privilege, attempt to protect people with AIDS. There are clinics which have procedures for anonymous testing. These clinics use number identifiers to protect patient confidentiality. However, the patient must appear at the clinic where he or she could be recognized by anyone else at the clinic. Accordingly, complete anonymity is difficult to maintain.

Tests have been developed and marketed that allow people to take a blood sample at home and mail it to a medical laboratory for analysis, e.g., Briggs et al. United States

Patent Nos. 4,777,964 and 4,979,515. These tests offer anonymity because the user does not appear at a laboratory, hospital or doctor's office. These tests, however, do require the person taking the test to give the laboratory his or her name and address. Thus, total anonymity for the person being tested is lost thereby discouraging people from taking the test.

Furthermore, the previous personal testing kits have only required the user to supply one blood sample. While often this is sufficient for accurate results, sometimes more than one blood sample is required because multiple tests are needed. It is important to make sure that the results to HIV antibody tests are accurate because of the severe consequences, e.g. death and discrimination, of a positive result.

Accordingly, a medical testing system is needed that is particularly designed to test for the HIV virus and allow the user to be completely anonymous. The test should also supply the medical lab with enough blood samples to ensure that the test result is as accurate as possible. The presently described invention addresses these mentioned needs.

SUMMARY OF THE INVENTION

In view of the above, and in accordance with the present invention, there is provided a method and system of testing for a human malady in private. One such human malady would be HIV. The test is privately conducted and the test results are anonymously reported to the person taking the test without revealing his or her identity. The method includes the steps of procuring a kit that is capable of taking a suitable test specimen from the person being tested. The kit has a unique personal code associated with it and all the necessary equipment for the person taking the test to be able to obtain the test specimen in private. The person taking the test proceeds by creating or activating

a personal electronic file through a telephone operated software program. The electronic file that is set up is identified by the personal code assigned to the kit. The electronic file is a data file for demographic information about the individual. At this time, the person taking the test can also be offered pretest counseling regarding the test and the test results.

The method continues with the person taking the test using the equipment provided in the kit to obtain the test specimen. In the situation where the person taking the test is concerned about AIDS, the test specimen is a blood sample. Once there is a test specimen, the next step is sending the test specimen for analyzation; the test specimen is sent with only the personal code to identify the person taking the test.

After the specimen is sent and the personal electronic file is created, the next step is analyzing the sample to obtain results. In the situation where the person taking the test is concerned about HIV, the ELISA and Western Blot methods to determine if the HIV antibodies are present in the test specimen. Other tests can be performed on the test specimen to detect a variety of diseases. Once the analyzation step is completed, the electronic file identified by the personal code that corresponds to the personal code of the test specimen is updated by adding the results.

After a sufficient period of time for analyzation and adding the results to the personal electronic file has elapsed, the next step is telephonically accessing the test results in the personal electronic file through the telephone operated software program using the personal code, thereby maintaining anonymity.

Depending on the results of the test, the telephone operated software proceeds by sending the person to the appropriate source to receive the results. If the test results

show the presence of a human malady, the person taking the test is told the results and counseled by a counselor who does not know the identity of the person. On the other hand, if the test results show no human malady, the individual is told by the telephone operated software program and is encouraged to speak to a counselor if there is any reason to do so.

The test system herein permits anonymous testing for a particular human malady, and the system includes a kit having the necessary equipment for producing a suitable test specimen from a person being tested which is capable of being transported from one location to another location for analyzation. The kit allows the specimen to be collected in private. To maintain anonymity, a personal code identifies the person being tested and the test specimen. An electronic file is created and accessible by the person being tested and is identified by the same personal code. The electronic file has entered into it the results of the analysis after the test specimen is analyzed.

As mentioned above, the test kit is equipped with all the proper equipment that an individual will need to acquire a test specimen. When the kit is used to test for HIV, the equipment will obtain a blood sample that is sufficient to analyze for HIV antibodies using the ELISA method and the Western Blot method. The kit comes equipped with an alcohol swab to clean an area of the skin, preferable the tip of the middle or ring finger, before the blood sample is taken, and at least two lancets that can puncture the skin so that blood can be acquired. A sterile gauze pad is provided to clean away the first drop of blood which is not suitable for the blood sample. The blood sample is produced by placing enough blood on a specially designed blood specimen collection card provided in the kit to fill preferably four specimen spots.

The collection card is preferably configured as a three part card. The first part of the card has printed thereon the personal code and a telephone number that is used by the person being tested to create the personal electronic file. The second part is an informed consent form with an area to be anonymously filled in by the person being tested with the personal code. The third part is special paper with specimen spots outlined thereon for the person being tested to create specimens for testing. The test kit further includes at least one bandage to protect the puncture after the blood sample is produced.

To send the kit to the medical lab, the kit is supplied with a foil lined envelope where the individual inserts the collection card and a drying agent. The foiled lined envelope is placed in a specially marked specimen bag that is also sealed. The waste is placed in another specially marked waste bag that is also sealed. The specimen bag and the waste bag are placed in a container, which is then placed in a mailing envelope and sent for analyzation and disposal, respectively. Alternatively, the waste can be disposed of locally.

These and numerous other objects, aims and advantages of the present invention will become readily apparent from the following detailed description, appended claims, and the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGURE 1 depicts the outer box that holds the contents of the medical testing equipment of the presently disclosed invention:

FIGURE 2 illustrates the box of FIGURE 1 in its open state with an exploded view of the testing equipment;

FIGURE 3 illustrates the sealed bag and the enclosed equipment in block form of the present invention;

FIGURE 4A & 4B are detailed drawings of the blood specimen collection card;

FIGURE 5 is a flow chart showing the steps a user takes to obtain a blood specimen;

FIGURE 6A & 6B illustrate the elements of the electronic file; and

FIGURE 7 is a flow chart showing the operation of the telephone operated automated software associated with the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

While the present invention is susceptible of embodiment in various forms, there is shown in the drawings and will hereinafter be described a preferred embodiment of the invention with the understanding that the present disclosure is to be considered as setting forth an exemplification of the invention which is not intended to limit the invention to the specific embodiment illustrated.

Referring now to the drawings, wherein like reference numerals indicate like parts throughout the several views, the present invention is an anonymous testing system which utilizes a kit 10 as a primary component thereof. As shown in FIGURE 1, kit 10 includes an outer box 12 used to package and mail the kit 10. Multiple tabs 14 inserted into multiple slots 16 are provided to keep the box 12 in its folded and secure position as shown in FIGURE 1. FIGURE 2 illustrates how when tabs 14 are removed from slots 16 box 12 can be unfolded to reveal the enclosed equipment which are used for the anonymous medical test.

All equipment in the medical test comes confined in a vacuum sealed clear plastic bag 18 as shown in FIGURE 3. The clear plastic bag allows the person being tested to examine the contents of the test to determine if all the necessary parts are provided.

The necessary components for the test are also revealed in FIGURES 2 and 3. The equipment preferably includes: 1) an alcohol swab 20; 2) at least two lancets 22; 3) a gauze pad 24; 4) a blood specimen collection card 26; 5) at least two bandages 28; 6) a drying agent (desiccant) 30; 7) a storage packet 32; 8) a specimen bag 34, and 9) a waste bag 36. A mailing envelope 38 may also be provided with the kit 10 to facilitate returning a test specimen for analyzation.

Alcohol swab 20 is preferably a 1 1/4 inch by 2 5/8 inch single fold, nonwoven applicator swab saturated with 70% isopropyl alcohol. To prolong the usefulness, swab 20 is preferably packaged in a foil tear-open packet, and can be of the type produced by Baxter Healthcare Corporation. Alcohol swab 20 is used to clean an area of skin from which blood will be drawn.

Lancets 22 are preferably single use lancets with a blade width of 1.0 mm and blade depth of 2.2 mm such as Becton Dickinson Microtainer Brand "Yellow" Safety Flow Lancets. Lancets 22 are used to puncture the cleaned skin of the user.

Gauze pad 24 is preferably a 2 inch by 2 inch sterile 12-ply sponge pad of 100% cotton USP Type VII gauze like that manufactured by Johnson & Johnson. Gauze pad 24 is used to clean and dry the skin around the puncture area.

The bandages 28 provided are preferably 1 inch by 3 inch sterile wrapped adhesive strips of the type manufactured by Johnson & Johnson as Band-Aid® brand bandages. The bandages 28 are used to cover the punctured skin after blood samples are taken.

The drying agent 30 can be any desiccant, but is preferably a silica gel like the one produced by U.D.G of Belen, New Mexico and marketed as Sorb-It®.

FIGURES 4A and 4B illustrates the blood specimen collection card 26 which is preferably a 4 1/2 inch by 3 1/2 inch diagnostic form having three (3) parts. The first part is a removable top sheet 40. Perforations 42 are preferably provided to enable the person being tested to remove the top sheet 40 from the remainder of the collection card 26. Printed on top sheet 40 is information that the person being tested needs to retain after the remainder of the collection card is sent for analysis. This information includes a personal code 44 and a phone number 46.

Personal code 44 is used to identify the blood specimen and the person being tested rather than a name and/or address. The personal code 44 is a randomly assigned number to the kit 10 so that each kit has a unique code 44 associated therewith. Because each number is unique, the person being tested can remain completely anonymous while having his or her blood specimen analyzed. As shown in FIGURE 4A, the personal code 44 is preferably an eleven (11) digit number. Nine digits, indicated by "0"s, are randomly assigned and the remaining two digits, indicated by "X"s, are used as a check sum to assure accuracy each time the number is used. It should be noted that any other system of identification can be used as long as the indicators are randomly assigned to each kit 10. The telephone number 46 allows the user to access the telephone operated software program 48 to generate a personal electronic file 50 and to access the results of the test, which will be discussed below.

The second part of collection card 26 is an informed consent form 52. The informed consent form 52 contains a series of statements that the person being tested must

read, understand, and acknowledge before a laboratory can perform any test on the specimen. The informed consent form 52 is returned along with the specimen. The consent form 52 has a space 54 which the individual fills in thereby acknowledging having read and understood the statements. To keep the anonymity of the person being tested, the user fills in the space 54 with the personal code 44.

The third part of collection card 26 is a blood specimen sample sheet 56. Sample sheet 56 is made of at least in part a cotton fiber filter paper preferably like that manufactured by Schleicher and Schuell® as #903™. Sample sheet 56 has similarly shaped sections 58 outlined thereon. In the preferred embodiment, four sections 58 are used so that the individual will provide at least four specimens for analyzation. The sections 58 are outlined using black biological ink so that the ink will not interfere with the specimen and an accurate test result can be obtained. It is best if the shapes are circles of approximately 0.375 inches in diameter. The sections 58 are spaced adequately apart so that the four different specimens will not be commingled and that acquiring the specimens will not be too difficult. Also placed on the sample sheet is a bar code 60 that has the same personal code 44 as was randomly assigned to the top sheet 40. The bar code 60 is used by the laboratory to identify the specimen as belonging to the person being tested who has been assigned the corresponding personal code 44. Accordingly, the person being tested and assigned the personal code 44 can be updated with the results of the analyzation.

Storage packet 32 is opaque and is preferably a foil lined envelope. As shown in FIGURE 2, the top edge 62 has an adhesive strip 64 covered by removable silicon strip. The dimensions of storage packet 32 are large enough to hold the collection card 26.

After the test specimen has been completed, it is inserted within the storage packet 32 along with the drying agent 30.

After the collection card 26 and drying agent 30 are deposited within the storage packet, the silicon strip is removed from the adhesive strip 64 and the top edge 62 is folded down so that the adhesive strip 64 sticks to the outside of the storage bag 32 thereby sealing the storage packet 32 closed. Specimen bag 34 is a clear plastic bag that can be securely sealed along its upper edge and is large enough to hold the storage packet 32. On the outside surface of the specimen bag 34, there is a label 66 preferably stating "specimen" so that the purpose and contents of the bag are clearly stated. The waste bag 36 is also a clear plastic bag that can be securely sealed along its upper edge. Waste bag 36 also preferably has a label 68 stating "Caution Biohazard" along with the typical biohazard symbol so that the contents of the bag 36 are readily identified as medical waste. The waste bag is large enough to hold the remaining and used elements of the test system 10, e.g. the lancets 22 and gauze 24.

Mailing envelope 38 is preferably a typical express mail type envelope used by e.g., Federal Express® or the United States Postal Service.® The mailing envelope 38 should be sufficiently large enough to hold the box 12 therein for sending to the laboratory.

FIGURE 5 illustrates the use of the kit 10 and the equipment described above. To begin, the user opens up the box to reveal the testing equipment (See FIGURES 1 and 2). The kit 10 can also contain an instruction booklet (not shown) which serves to help the person being tested obtain a specimen and answer any questions.

Initially, the person being tested should activate the personal code 44 assigned to the kit 10 using the telephone automated software program 48. The user will find the assigned code 44 on the top sheet 40 of the collection card 26. Also on the top sheet 40 is the telephone number 46 the person being tested calls to activate the personal code 44. By using the push buttons of the telephone, the user registers the code 44 at a central location. If the user does not have a touch tone telephone, a counselor will be provided to activate the personal code 44.

When the person being tested telephones to activate the personal code 44, the telephone automated software program 48 collects demographic information, and the person being tested is preferably offered pre-test counseling. The demographic information will not include any information that would divulge the true identity of the person being tested. The type of information sought concerns the sex and age of the person being tested, and the person's zip code and is inserted into a database electronic file 50 as depicted in FIGURE 6. Organizations like a local health department the Center for Disease Control in Atlanta, Georgia can then use this information for statistical purposes in its monitoring of the AIDS epidemic.

The pre-test counseling is an opportunity for the central location to help the person being tested cope with the possibility that the results from the test will be positive. A counselor will ask a series of questions like, "What do you expect your test results to be?" "What would you do if your test results are positive?" "Who could you rely on for support if your test results are positive?" etc.

The person being tested must also acknowledge that he or she has read and understood the informed consent form 52 on the collection card 26. The informed

consent form 52 has a series of statements informing the user about the test, the meaning of the results, and authorizing a medical laboratory to test the blood specimen sent to it for the presence of HIV antibodies. In order to protect anonymity, the person being tested is reminded to fill in the consent form 52 with the assigned personal code 44 rather than sign his or her name. The consent form 52 should not be removed from the collection card 26.

The person being tested then selects and cleans a skin area with soap and water. To assure cleanliness, the alcohol swab 20 is preferably used to further clean an area. The skin area can be from any part of the body, but the tip of the middle or ring finger is preferable. After the finger is cleaned, the person being tested should dry the finger tip with the sterile gauze pad 24.

The person being tested opens one of the two lancets 22 provided which will be used to puncture the cleaned area thereby producing a flow of blood. In order to effectively use the lancet 22, the person being tested should stabilize the finger such as on a flat hard surface and position the lancet 22 between the fore and middle fingers of the opposite hand. The lancet 22 is then placed against the pad of the finger tip thereby causing a dimple. When the person being tested is ready, the lancet's plunger is depressed and held for a split-second. This motion causes the blade of the lancet to puncture the skin thereby producing a flow of blood. After the puncture is created, the lancet is removed from the finger area, and the first drop of blood is wiped away by the sterile gauze pad 24. Another drop of blood should develop soon thereafter.

Next, the person being tested applies the drops of blood developing on the finger tip to the sample sheet 56 of the collection card 26 by gently touching the finger to each

of the separate specimen sections 58 after a large drop of blood has developed. The person being tested should keep the sample sheet 56 in contact with the finger to allow a sufficient quantity of blood to soak through sample sheet 56 and fill the specimen sections 58. Each of the specimen sections 58 provided should be filled in a similar fashion.

If the person being tested has problems producing enough blood from the puncture to fill each specimen section 58, the person can use another lancet 22 to create a second puncture area on the finger thereby causing blood to flow from a different spot. The second lancet should be used because of the problem using the first one again. The lancets 22 are designed for single use and attempting to use a lancet 22 twice might not produce a flow of blood.

After all the specimen sections 58 are completely filled, the person being tested can bandage the area puncture with one of the bandages 28 that is provided.

Once the person being tested has acquired the necessary blood sample on the collection card 26, the collection card 26 and waste is preferably prepared for sending away where they will be analyzed and disposed of, respectively. Alternately, the waste can be disposed of locally. The drying agent 30 is inserted into the storage packet 32 and followed by the collection card 26. The silicon strip is removed, and the top edge 62 of the storage package 32 is folded over so that the adhesive strip 64 sticks to the outside surface of the storage packet 32 thereby sealing the collection card into the storage bag 32. After the storage packet 32 is sealed, the person being tested inserts it into the specimen bag 34, which is sealed at its top edge.

The person being tested then places the remaining equipment into the waste bag 36. The items to be placed into the waste bag 36 preferably include the used alcohol swab 20, the lancets 22 provided, regardless if they have been used or not, the used gauze pad 24, and the remaining bandages 28 along with any wrappers or packaging. The only thing that ought to remain outside either the specimen bag 34 or the waste bag 36 should be the top sheet 40 which the user needs for future reference.

The person being tested then takes the specimen bag 34 and the waste bag 36 and puts them into the box 12. The flaps 14 are inserted into the slots 16 so that the box is secured shut. Then, the person places the box 14 into the mailing envelope 38 so that the medical lab can receive the collection card 26 and the waste for testing and disposal, respectively.

After the blood sample has been sent to the laboratory for testing, the user should wait a number of days before analysis can be performed on the specimen and the results relayed to the user. When the laboratory receives the collection card 26, it will perform the ELISA test to detect for HIV antibodies. If the ELISA test is positive, the Western Blot test will be performed to confirm a positive result. When the results of the test are known, the laboratory will update the electronic file 50 set up by the person being tested that corresponds to the bar code 60. After the electronic file 50 is updated, the person can access the test results. It should take approximately seventy-two hours after the laboratory has received the collection card 26 to update the electronic file 50.

In order to obtain the test results, the person will call the phone number 46, which can be found on the retained top sheet 40. If the test results are negative, the telephone-operated computer software program 48 will so inform the user. On the other hand, a

counselor will inform the user of the positive results. This way the user can be told how to get the proper medical attention and to determine if the user has possibly infected others with the HIV virus. At no point in the process is the identity of the user revealed. Also if the test results are positive, the local health department and/or the Center for Disease Control can be informed.

FIGURE 6A & 6B illustrates the elements of the personal electronic file 50 that is created by the person being tested when he or she telephones the telephone automated computer program 48 to activate the personal code 44 assigned to the kit 10. The electronic file 50 is a computer database file that holds all the relevant non-identifying data about the person being tested. The electronic file 50 has at least two area; a patient record 70 and a call log 72. The patient record holds relevant information about the person such as the personal code 44, the sex, birth date, zip code, whether the person has been tested before, and test result. A call log 72 is set up for each time that the user calls. Each call log 72 is identified by the users personal code 44, and also designates the date and time of each call. There is also space for a counselor to put notes about each call.

The telephone automated software program 48 has been developed for people to set up and access their electronic files 60. When a person calls the telephone number 46, the person first accesses the telephone automated software program 48. FIGURE 7 is a flow chart illustrated the steps of the telephone automated software program 48. The program 48 preferably begins by asking if the user is calling to set up his or her electronic file 50, or calling to receive test results. (Step 1). The person being tested selects the appropriate number on the push button telephone depending on the response

to step one. If the person does not have a touch tone telephone, a counselor will answer the phone and proceed in collecting the relevant information.

If the person is calling to set up the electronic file, the program 48 asks the user to enter the eleven digit personal code 44. (Step 2). After the number is entered, the program 48 repeats the entered number. (Step 3). If the number repeated is incorrect, Step 2 is repeated, otherwise the program 48 proceeds by asking the person to complete the electronic file 50. (Step 4). After the electronic file 50 is completed, the program 48 connects the user to a counselor for pre-test counseling. (Step 5).

On the other hand, if the person being tested is calling to get results, the program 48 begins by asking the person to enter the eleven digit personal code 44. (Step 6). After the number is entered, the program 48 repeats the entered number. (Step 7). If the number repeated is incorrect, Step 6 is repeated, otherwise the program 48 proceeds so that the person will receive the test result. If the test results are negative, the program 48 so informs the person. (Step 8). Step 8 also encourages the user to talk to a counselor and to take the test again if there is any reason to believe that HIV antibodies will develop in the future. (Step 9)

If the test results are positive, the program 48 transfers the user to a counselor to inform the user of the results. (Step 10). Step 10 further takes the opportunity to counsel the person being tested about how to get proper medical attention, face-to-face counseling and to determine if there are any people that the user should inform about the test results because they might also be infected with the HIV virus.

It should be noted that the principles of an anonymous testing procedure as disclosed herein can be used for other diseases where the user does not want his or her

name disclosed. Furthermore, the procedure does not have to be limited to testing for diseases, but can be used in other fields.

From the foregoing, it will be observed that numerous modifications and variations can be effected without departing from the true spirit and scope of the novel concept of the present invention. It will be appreciated that the present disclosure is intended as an exemplification of the invention, and is not intended to limit the invention to the specific embodiment illustrated. The disclosure is intended to cover by the appended claims all such modifications as fall within the scope of the claims.

WHAT IS CLAIMED IS:

1. A method of testing for a particular human malady wherein the test is privately conducted and testing results are anonymously reported without revealing a person's identity, said method comprising the steps of:

procuring a kit for taking a suitable test specimen from the person being tested, said kit having a personal code associated therewith and equipment for obtaining said test specimen;

creating a personal electronic file telephonically, said electronic file being identified only by said personal code;

using said equipment to obtain said test specimen;

sending said test specimen for analyzation, said test specimen being identified only by said personal code;

analyzing said test specimen to obtain results;

adding said results to said electronic file; and

accessing said test results in said electronic file telephonically using said personal code thereby maintaining anonymity for the person being tested.

2. The method for anonymous testing according to Claim 1 wherein said test specimen comprises body fluid of the person being tested.

3. The method for anonymous testing according to Claim 1 wherein the test specimen comprises a blood sample of the person being tested.

4. The method for anonymous testing according to Claim 1 further comprising the step of counseling the person being tested without having the person reveal their identity when the person accesses said results.

5. The method of anonymous medical testing according to Claim 1 wherein said creating step including pre-test counseling.

6. A process for testing for antibodies to a Human Immunodeficiency Virus (HIV) which is responsible for Acquired Immune Deficiency Syndrome (AIDS) wherein test results are reported without having to reveal a person's identity, said method comprising the steps of:

procuring a test kit for taking a blood sample, said test kit having a personal code associated therewith and equipment for taking said sample;

creating a personal electronic file telephonically, said electronic file being identified only by said personal code;

using said equipment in private to obtain at least one blood sample;

sending said blood sample for analyzation, said blood sample being identified only by said personal code;

analyzing said blood sample for antibodies to HIV to obtain test results;

adding said test results to said electronic file; and

accessing said test results in said electronic file telephonically using said personal code thereby maintaining anonymity for the person being tested.

7. The method of anonymous testing according to Claim 6 wherein said using step further comprises:

cleansing an area of skin with disinfectant;

puncturing said skin to receive said blood sample;

depositing at least one sample capable of being analyzed on a blood specimen collection card, said card being identified by said personal code;

filling a first bag with said card, and

sending said first bag for analyzation.

8. The method of anonymous testing according to Claim 7 further comprising the steps of:

bandaging said punctured skin with a bandage after obtaining said blood sample, and

filling a second bag with waste from said cleansing step, said puncturing step and said bandaging step.

9. The method of anonymous testing according to claim 8 wherein said puncturing step includes the use of a lancet with a blade, said lancet being placed into said second bag during said filling step.

10. The method of anonymous testing according to claim 8 further comprising the step of filling a third bag with said first bag wherein said first bag is a foil lined envelope.

11. A test system for permitting anonymous testing for a particular human malady, said test system comprising:

a kit including equipment for producing a suitable test specimen from a person being tested which is capable of being transported from one location to another location for analyzation, said kit allowing said test specimen to be created in private;

a personal code for anonymously identifying the person being tested; and

an electronic file telephonically created and accessible by the person being tested and identified by said personal code and to which test results are entered following analyzation of the test specimen.

12. The anonymous testing system according to claim 11 wherein said electronic file further having demographic information about the person taking the test entered therein.

13. The anonymous testing system according to claim 11 wherein said equipment in said kit including an envelope for transporting said specimen from said one location to another location for analyzation.

14. A test system for permitting anonymous testing for antibodies to a Human Immunodeficiency Virus (HIV) which is responsible for Acquired Immune Deficiency Syndrome (AIDS), said system comprising:

a kit including equipment for producing a suitable blood sample from a person being tested which is capable of being transported from one location to another location for analyzation, said kit allowing said blood sample to be created in private;

a personal code associated with said blood sample for anonymously identifying the person being tested; and

an electronic file telephonically created and accessible by the person being tested and identified by said personal code and to which test results are entered following analyzation of said blood sample.

15. The anonymous testing system according to claim 14 wherein said personal code being a number.

16. The anonymous testing system according to claim 14 wherein said equipment of said kit comprising:

a skin cleansing device for cleansing an area of skin of the person being tested;

a skin puncturing device for producing a flow of blood from said cleansed area of skin, said blood sample being produced therefrom;

a blood specimen collection card for depositing said blood sample thereon, said collection card being identified by said personal code; and

an envelope for transporting said collection card with said blood sample thereon from one location to another location for analyzation of said blood sample.

17. The anonymous testing system according to claim 16 further comprising a shipping container to hold said blood specimen collection card.

18. The anonymous testing system according to claim 16 wherein said collection card comprising:

a tear-off information sheet having said personal code thereon;

an informed consent form having a place to be filled in by said person with said personal code; and

a specimen sheet for holding said blood sample and having said personal code thereon, said informed consent form remaining therewith.

19. The anonymous testing system according to claim 18 wherein said specimen sheet is a cotton fiber paper having at least four separated specimen spots for multiple blood samples from said person taking the test and said personal code being a bar code.

20. The anonymous testing system according to claim 16 further comprising:

a drying agent, and

a first bag for holding said collection card and said drying agent for transporting said blood sample from one location to another location for analyzation in said envelope.

21. The anonymous testing system according to claim 20 further comprising:

a second bag for holding said skin cleaning device and said skin puncturing device for suitable disposal thereof.

22. The anonymous testing system according to claim 20 further comprising:

a bandage for bandaging said skin after being punctured; and wherein

said cleansing device includes a alcohol swab and a gauze pad;

said skin puncturing device being at least one lancet having a blade;

said blood collection card including a tear-off information sheet having said personal code thereon, an informed consent form having a place to be filled in by said person taking the test with said personal code, and a specimen sheet for holding said blood sample and having said personal code thereon; and

said first bag being a foil lined envelope.

23. The anonymous testing system according to claim 22 wherein said specimen sheet being a cotton fiber paper with at least four separate specimen spots.

24. The anonymous testing system according to Claim 23 wherein said specimen spots are circles having 0.375 inch diameters.

25. The anonymous testing system according to Claim 22 further comprising a third bag to hold said foil lined envelope.

26. The anonymous testing system according to Claim 25 further comprising a shipping container to hold said second and third bag and to be placed in said mailing envelope.

27. A transport system for use with a kit for privately testing for a particular human malady, said kit having equipment for obtaining a specimen suitable for analyzation, said system comprising:

an envelope for holding said specimen;

a first bag for holding said envelope;

a second bag for holding said equipment;

a shipping container for packaging said first and second bags; and

a mailing envelope for shipping said container.

28. The transport system according to claim 27 where said envelope is foil lined, said first and second bags being clear plastic, and said mailing envelope being an overnight delivery type envelope.

29. The transport system according to claim 27 wherein said first and second bags further comprising labels indicating the contents therein.

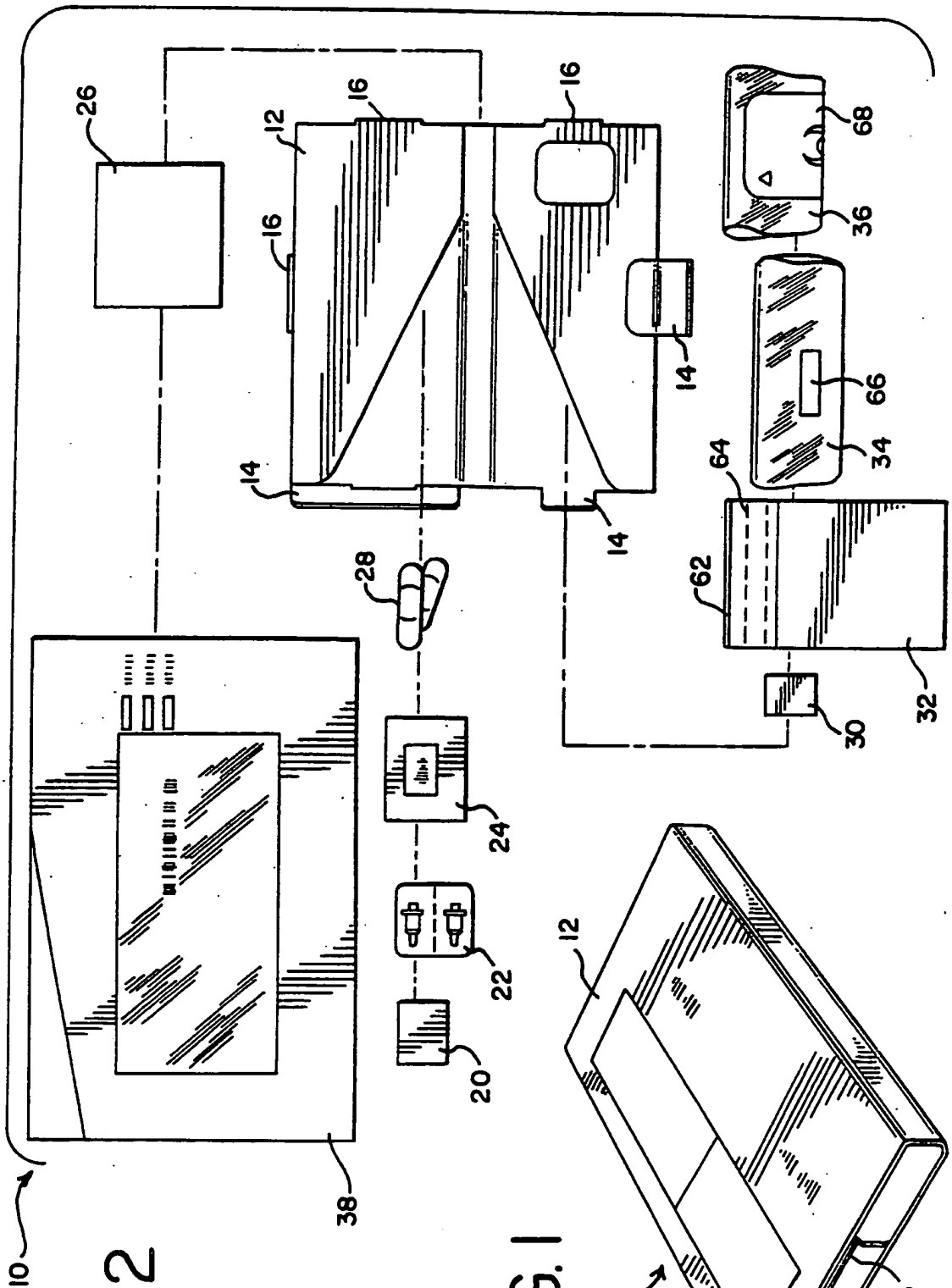


FIG. 2

FIG. 1

RECTIFIED SHEET (RULE 91)

FIG. 3

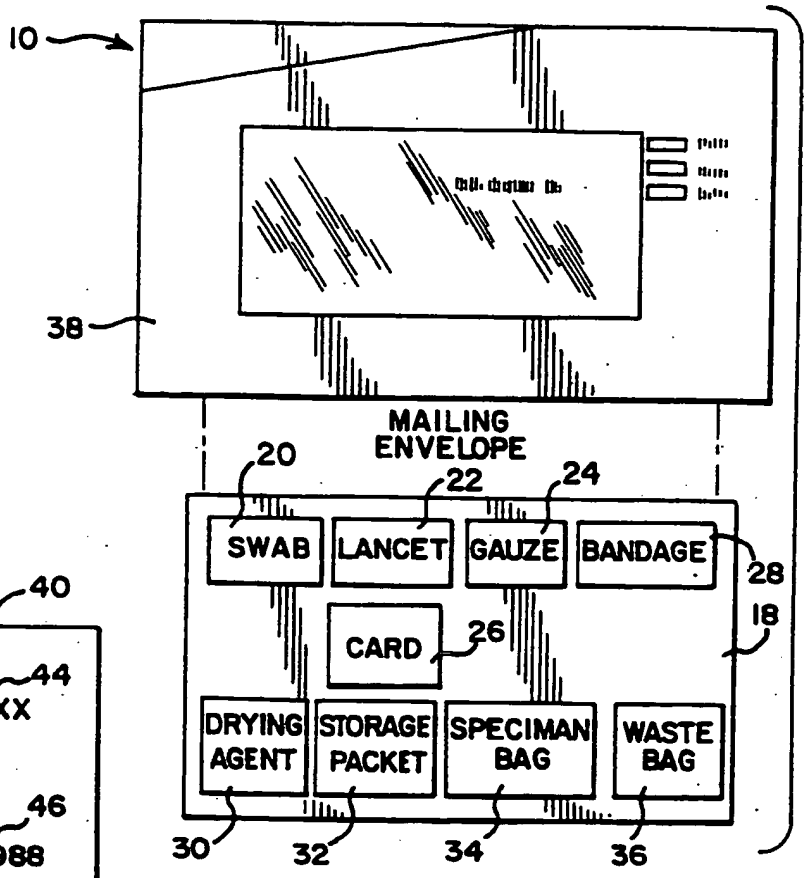


FIG. 4A

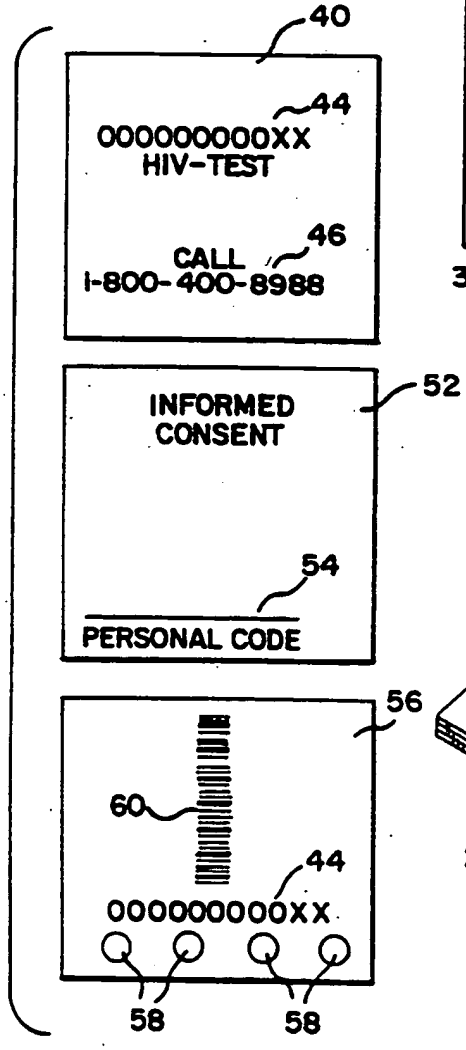
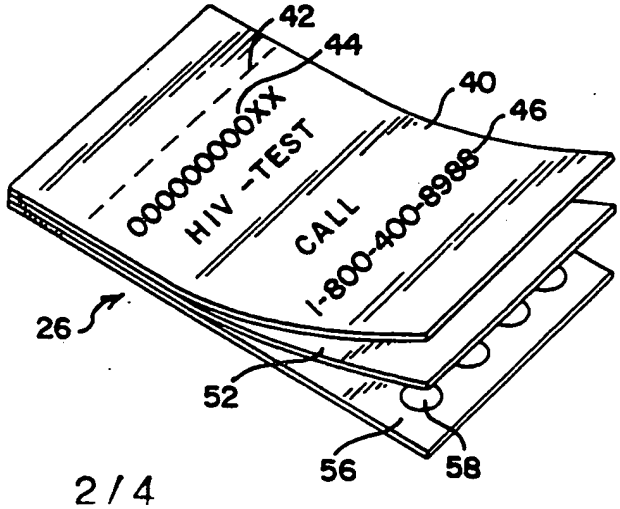


FIG. 4B



RECTIFIED SHEET (RULE 91)

FIG. 5

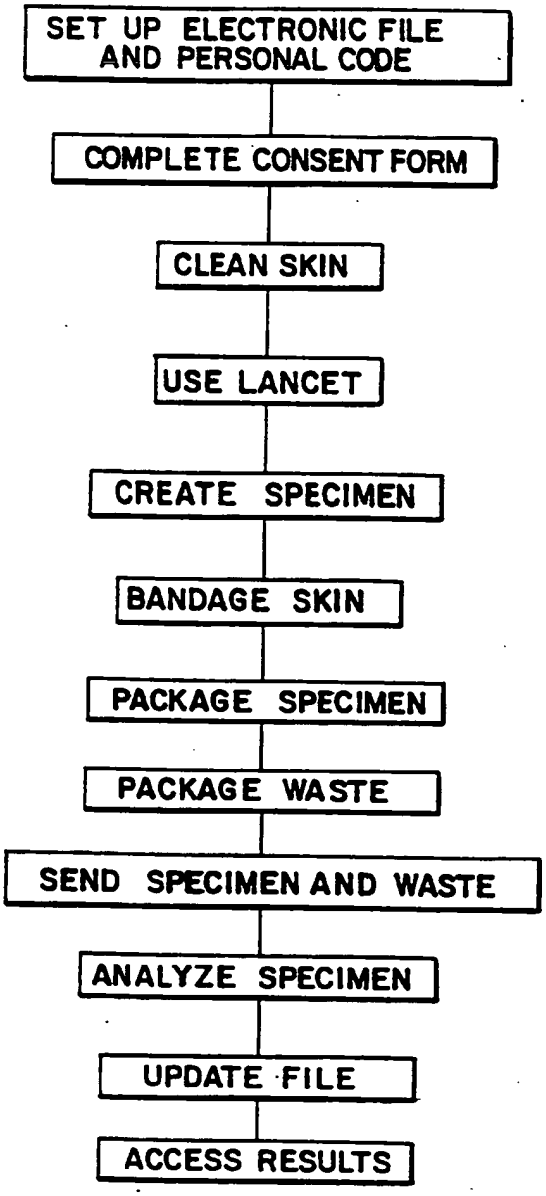


FIG. 6A

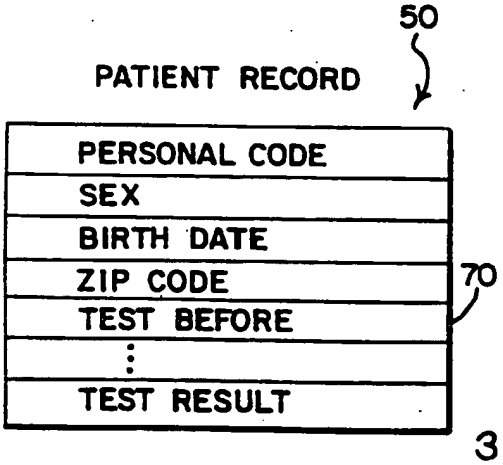
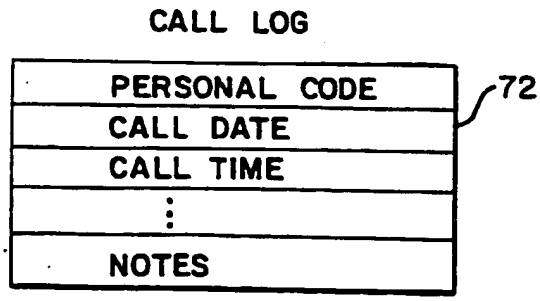
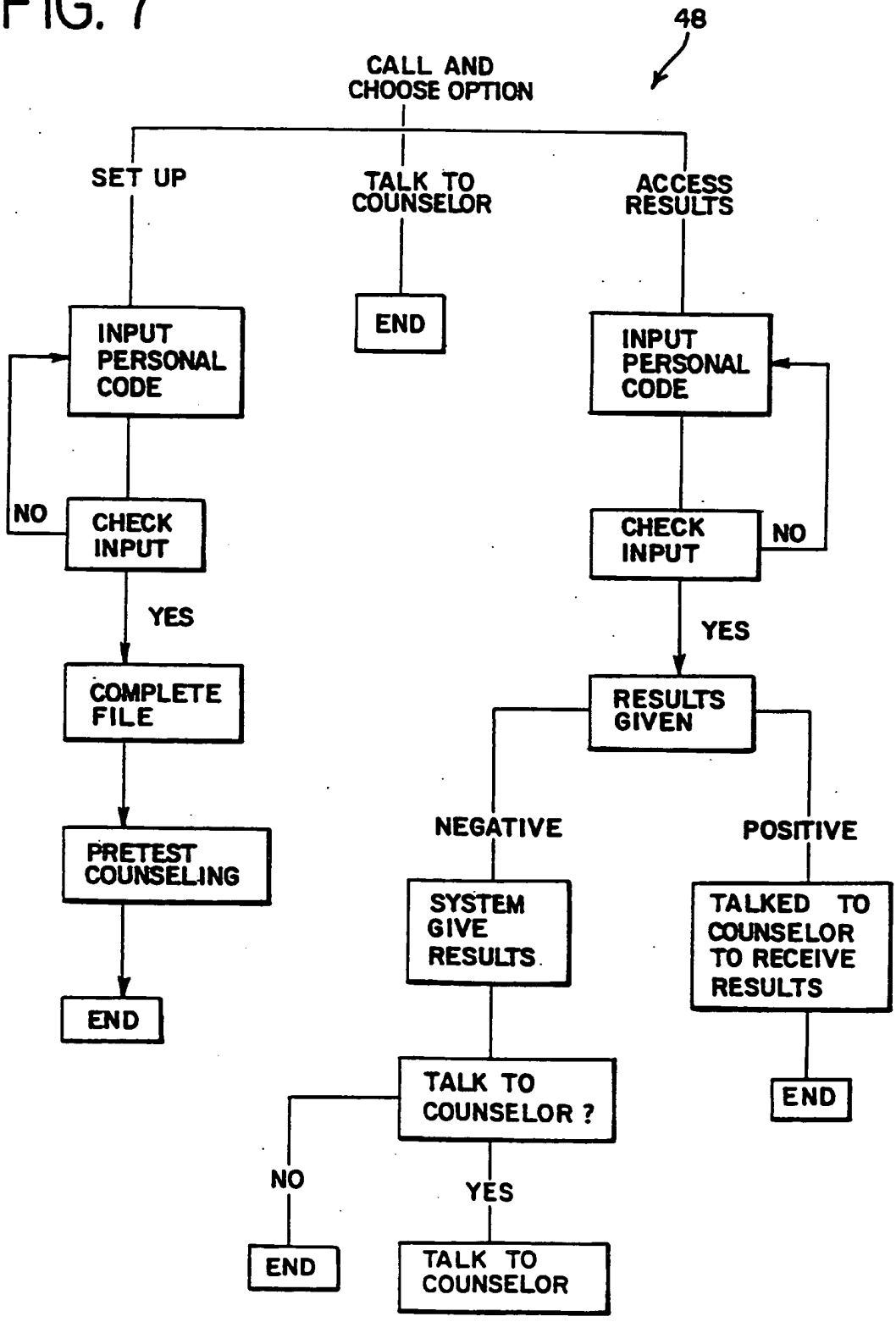


FIG. 6B



RECTIFIED SHEET (RULE 91)

FIG. 7



RECTIFIED SHEET (RULE 91)

INTERNATIONAL SEARCH REPORT

Inte ..onal application No.
PCT/US94/12623

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) : G01N 33/487, 33/49, 33/52, 33/53
US CL : 435/5, 6, 974

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 435/5, 6, 974

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

none

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

Dialog, APS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	Nature , Volume 332, issued 14 April 1988, Anderson, "Home test kits for AIDS blocked", page 573, see entire document.	1-6, 11, 12, 14, and 15
Y	American Journal of Hospital Pharmacy, Volume 47, Number 3, issued March 1990, DeChristoforo, "What is the Status of AIDS Antibody Home Test Kits?", page 619, see entire document.	1-6, 11, 12, 14, and 15
Y	US, A, 4,792,968, (KATZ) 20 December 1988, see columns 1 and 2.	1-6, 11, 12, 14, and 15
Y	US, A, 4,777,964, (BRIGGS et al) 18 October 1988, see entire document.	7-10, 13, and 27-29
Y	US, A, 4,277,249, (BROUGHTON) 07 July 1981, see column 2, lines 28-41.	16-26

[X] Further documents are listed in the continuation of Box C. [ ] See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
16 JANUARY 1995	07 FEB 1995

Name and mailing address of the ISA/US	Authorized officer
Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	JEFFREY STUCKER
Facsimile No. (703) 305-3230	Telephone No. (703) 305-0196

Form PCT/ISA/210 (second sheet)(July 1992)*

INTERNATIONAL SEARCH REPORT

Int ..tional application No.
PCT/US94/12623

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US, A, 5,156,948, (CHRISTENSEN et al) 20 October 1992, see column 4, line 67, to column 5, line 9.	1, 16-26
Y	US, A, 3,883,396, (THOMAS, JR. ET AL.) 13 May 1975, see column 1, lines 17-23 and column 2, lines 26-28.	1-6, 11, 12, 14, and 15